K023877

DEC 2 3 2002

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Lynn Harmer, Manager, Regulatory Submissions
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Date prepared: 19 November 2002

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	Q LAB Quantification Software with Strain Rate Quantification Plug-in
Classification Name:	Picture Archiving and Communications System, Class II

3) Device Description
The Q LAB software provides a means of opening and displaying image files, creating AVI and BMP files from the image data displayed by the software. The Strain Rate quantification plug-in module is designed to operate within the QLAB software by creating a "line of interest" (called "M-Line") that is overlaid on the image data displayed by the software. The plug-in analyzes the content of the image data contained within the M-Line figure, presenting the velocity, strain-rate and strain data in XY graphic and virtual M-Mode format. The software provides a means of exporting the data generated by the plugin module in a form accessible to the end user.

4) Performance Standards
No performance standards for PACS systems or components have been issued under the authority of Section 514. The Q LAB software has been designed to comply with the following voluntary standards:

MSDN - Microsoft Developer's Network October 2001
ISO Joint Photographic Experts Group (JPEG) Image Compression Standard

5) General Safety and Effectiveness Concerns
The device labeling contains operating instructions for the safe and effective use of the Q LAB software.

6) Substantially Equivalent Devices
Philips Ultrasound believes that the Strain-Rate Imaging quantification capabilities of the Q LAB software make it substantially equivalent to other commercially available products, specifically GE's Strain-Rate software.

7) Software
Software development for the Q LAB software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product.

8) Conclusions

The Q LAB software is designed and manufactured to meet United States and international standards for the display and quantification of images acquired on Phillips Ultrasound devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. The Q LAB software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2002

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K023877
Trade/Device Name: Q LAB Quantification Software with Strain Rate Quantification Plug-in
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 19, 2002
Received: November 21, 2002

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix A – Indications for Use

Device Name: Q LAB Quantification Software with Strain Rate Quantification Plug-in

Indications for Use:

The Q LAB Quantification software is a Windows 2000/Windows XP software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

Prescription Use /

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023877